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REMARKS

The above listed claim amendments along with the following remarks are fully responsive to the Office Action set forth above. In that Office Action, the Examiner rejected claims 28-34. By this Amendment, the Applicant hereby submits terminal disclaimers to obviate rejections on the ground of nonstatutory obviousness-type double patenting. Additionally, claim 28 is amended to correct a typographical error in the claim as originally presented. No new matter has been added. Claims 28-34 are currently pending.

Double Patenting

The Examiner rejected claims 28-34 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over certain claims of U.S. Patent Nos. 6,544,168, 6,375,608, 6,165,122, 6,077,218, 5,702,343, 6,126,590, and 6,165,121. Additionally, the Examiner has provisionally rejected claims 28-34 on the ground of non-statutory obviousness-type double patenting as being unpatentable over certain claims of co-pending U.S. Patent Application Nos. 10/668,460, 10/668,528, and 10/661,918. The Applicant traverses the double-patenting rejections by submitting herewith terminal disclaimers relating to each of the above-identified U.S. patents and applications. Withdrawal of the rejections on the ground of non-statutory obviousness-type double patenting is respectfully requested.

Claim Rejections – 35 USC § 103(a)

Claims 28-34 stand rejected under 35 U.S.C. §103(a) based on U.S. Patent 6,508,756 (“Kung”) in view of U.S. Patent 4,957,477 (“Lundback”). The Applicant respectfully traverses.

The Kung patent discloses, in relevant part, a “girdle” for limiting the maximum diastolic dimension of the heart. As disclosed, “a number of interlinked two-dimensional loops such as lightweight plastic rings 133 are interconnected to form the girdle or wrap 130.” No materials for the rings other than “plastic” are disclosed. In particular, as the Examiner acknowledges, the Kung patent does not disclose the use of a radio-opaque

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material in the girdle. Nevertheless, the Examiner has combined the Kung and the Lundback patents in the above-identified Office Action, relying on the Lundback patent for disclosing the use of radio-opaque materials. The Applicant respectfully submits that the Examiner has improperly combined the Kung and Lundback patents in rejecting claims 28-34.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation to combine the teachings of the cited references. This suggestion or motivation to combine the cited references can be found either in the nature of the problem to be solved, the teachings of the references themselves, or the knowledge of persons of ordinary skill in the art. *See In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998). The Examiner asserts that “[i]t would have been obvious to use radiopaque materials with the device of Kung since such would allow for checking the device when the patient’s chest is closed.”

The Applicant respectfully disagrees with this position. First, although the Lundback patent mentions that the hear assist device disclosed therein may be made of radiopaque materials, it fails to provide any teachings or description as to the function or utility of the radiopacity of such materials. Second, the Kung patent neither teaches nor suggests any procedure for “checking the device when the patient’s chest is closed.” Moreover, the Kung patent actually teaches away from the use of radio-opaque materials in its girdle. In the Kung patent, the only disclosed post-implantation procedure (i.e., a procedure performed when the patient’s chest is closed) for the interlocked ring girdle of FIGS. 22-23 relates to re-sizing of the girdle. The Kung patent teaches that such re-sizing is accomplished via strings which can be pulled to “accommodate a treatment modality for scheduled size reduction to the heart over as suitable period of time.” See FIG. 23 and C.19:34-46 (emphasis added). Thus, Kung teaches that the post-implantation size adjustments are time-based, not based on any fluoroscopic monitoring “after the chest is closed.” Moreover, as disclosed in the Kung patent, pulling of the strings “can be done during a thoracoscopy or through a cutaneous access port,” i.e., under direct visual access to the girdle. In short, the Kung patent teaches

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away from post-implantation examination "when the patient's chest is closed" aided by radio-opaque materials in the jacket.


In contrast, claim 28 explicitly recites, in part, a jacket constructed of a radiopaque biomedical material. The claimed jacket provides numerous advantages over the prior art. For example, the claimed jacket provides a reduction in cardiac dilation. The claimed CRD jacket also provides for monitoring and measuring cardiac performance aided by, for example, radiopaque materials in the jacket. As explained above, this is neither disclosed nor fairly suggested by the Kung patent. Because, as also explained above, the required suggestion or motivation to combine the Kung and Lundback patents is lacking, claim 28 is believed to be patentable over the teachings of the cited prior art. Additionally, claims 29-34, which depend from claim 28, are also believed to be patentable over the cited references for at least the same reasons. Reconsideration and withdrawal of the rejections under 35 U.S.C. § 103 is respectfully requested.

The Applicant respectfully requests that a Notice of Allowance be issued in this case.

Respectfully Submitted,

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